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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,514	11/17/1998	MIE KAINOH	1102-98	8751

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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/155,514

Applicant(s)

KAINOH ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,7-9,25,50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3,8,9,25,50,52 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1. Applicant's election without traverse of the species $\alpha 2\beta 1$ in the reply filed on 6/28/04 and 10/5/04 is acknowledged.
 2. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/28/04 and 10/5/04.
 3. Claims 3,8,9,25,50,52 are under consideration.
 4. The rejection of claim 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action are withdrawn in view of the cancellation of said claim.
 5. The rejection of claims 2-9,25,50,51 under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and Presta et al.(US Patent 6,025,166) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of the specification) is withdrawn in view of the amended claims, applicants arguments and the cancellation of claims that have been cancelled.
 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3,8,9,25,50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. (WO 95/17412) in view of Schneck et al. (US Patent 6,015,884), Takada et al. and Presta et al. (US Patent 6,025,166).

The specification, page 11 discloses that "chimeric protein consisting of the α or β chain of an integrin and the heavy or light chain of an immunoglobulin" actually means the extracellular region of the α or β chain of an integrin is bound to the constant region of the heavy chain or light chain of an immunoglobulin. Gallatin et al. teach fusion proteins containing the extracellular domain of an integrin chain (including an α chain) attached to a human Ig constant domain region (see claim 19 and page 37) wherein the order of the components indicates that the integrin chain is connected to the Ig constant domain at the c terminus of the integrin molecule. Gallatin teach drug compositions of such molecules (see page 12). Gallatin et al. do not teach that the molecule is a heterodimer of an $\alpha 2$ chain/Ig heavy chain constant region attached to a $\beta 1$ /Ig heavy chain constant region. Schneck et al. discloses fusion proteins wherein an α chain of an integrin is attached to one chain of an Ig molecule and a β chain is attached to a different chain of an Ig molecule wherein dimers are formed between the two molecules (see column 8, last paragraph and column 11, first and third paragraphs). Takada et al. disclose that VLA-2 (aka $\alpha 2\beta 1$) exists as a heterodimer wherein the amino acid sequence of the $\alpha 2$ and $\beta 1$ chains were known in the art (see abstract, page 398, first column and Figure 2). Presta et al disclose Ig fusion molecule heterodimers that contain two Ig heavy chain constant regions wherein the molecules are linked by a disulfide bond (see column 5, first paragraph) and that the construct contains cysteines in the heavy chain which mediate formation of disulfide bonds between the two heavy chains (see column 36, first paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gallatin et al. teach fusion proteins containing the extracellular domain of an integrin chain attached to a human Ig constant domain regions, Schneck et al. discloses fusion proteins wherein an α chain of an integrin is

attached to one chain of an Ig molecule and a β chain is attached to a different chain of an Ig molecule wherein dimers are formed between the two molecules, Takada et al. disclose that VLA-2 (aka $\alpha 2\beta 1$) exists as a heterodimer wherein the amino acid sequence of the $\alpha 2$ and $\beta 1$ chains were known in the art whilst Presta et al disclose Ig fusion molecule heterodimers that contain two Ig heavy chains wherein the molecules are linked by a disulfide bond and that the construct contains cysteines in the heavy chain which mediate formation of disulfide bonds between the two heavy chains. Presta et al. disclose that the Ig constant regions used in said molecules are known in the art (see column 33) and that the fusion protein could contain any art known Ig isotype (see column 33, third paragraph). One of ordinary skill in the art would have been motivated to do the aforementioned because Schneck et al. discloses fusion proteins wherein an α chain of an integrin is attached to one chain of an Ig molecule and a β chain is attached to a different chain of an Ig molecule wherein dimers are formed between the two molecules, whilst Presta et al. disclose that the simplest and most straightforward immunoadhesin fusion molecule contains the extracellular domain of the binding domain attached to Ig heavy chain constant regions (see column 33, last paragraph, continued on next page) and Ig fusion molecule heterodimers that contain two Ig heavy chains wherein the molecules are linked by a disulfide bond. The sequences recited in claims 8 and 9 represent the aforementioned art known $\alpha 2$ and $\beta 1$ sequences attached to art known Ig constant region sequences.


8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644